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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/741,664	12/21/2000	Ayoub Rashtchian	0942.3910003/RWE/BJD	7736
26111	7590	09/25/2006	EXAMINER	
STERNE, KESSLER, GOLDSTEIN & FOX PLLC 1100 NEW YORK AVENUE, N.W. WASHINGTON, DC 20005			SITTON, JEHANNE SOUAYA	
			ART UNIT	PAPER NUMBER
			1634	

DATE MAILED: 09/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/741,664

Applicant(s)

RASHTCHIAN ET AL.

Examiner

Jehanne S. Sitton

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 60 and 61 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 60-61 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/19/2006 has been entered.

2. Currently, claims 60 and 61 are pending in the instant application. Claims 1-59 are canceled. The rejections made in the previous office action are moot in view of the cancellation of the claims. All the amendments have been thoroughly reviewed but are deemed insufficient to place this application in condition for allowance. The following rejections are newly applied to the newly added claims. They constitute the complete set being presently applied to the instant Application. The following action is NON-FINAL.

3. Should any subsequent claim amendments to this office action be made which require new grounds of rejection using art previous made of record, finality of any subsequent office action will not be affected.

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

5. Claims 60 and 61 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims recite the phrase “removing from storage”. The specification does not define the term storage. It is unclear if the claim intends that the term “storage” is meant to signify storage under certain conditions or for a set amount of time. The specification does not define the term. Accordingly, the metes and bounds of the claim are unclear.

The claims recite the term “then” after step a. It is unclear if the term is meant to limit that the method such that step b) occurs immediately after step a) and that therefore no intervening steps can occur, or that intervening steps can be performed between steps a) and b). If the latter is the case, it is unclear, in claim 61, if the term “contacting said thermostable DNA polymerase” limits contacting only the thermostable polymerase, alone, with the sample nucleic acid, but not the dNTP or the buffer. Without an intervening extraction step, it is unclear how one would be capable of contacting only the polymerase with the sample nucleic acid without also contacting the dNTP and the buffer with the nucleic acid as well. The specification does not provide any guidance regarding such. Additionally, if the latter is the case, it is unclear what is meant by the term “composition”. Normally, the term is meant to signify that certain elements are found together in a mix, for example, in the same solution. Therefore, if the polymerase, buffer, and dNTP are in the same solution, how can one only contact the polymerase with the nucleic acid sample?

In claim 61, it is unclear if the phrase “contacting said thermostable DNA polymerase” limits contacting only the thermostable polymerase, alone, with the sample nucleic acid, but not the dNTP or the buffer, or if it includes contacting the entire composition from step a) with the sample nucleic acid. If the latter is the case, it is further unclear how the scope of claims 60 and 61 differ.

6. Claim 61 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Newly added claim 61, recites that step a) requires removal of a composition comprising a thermostable DNA polymerase, a dNTP and a buffer salt, then, b) contacting said thermostable polymerase with sample nucleic acid molecules. As noted above in rejection under 35 USC 112/2nd paragraph, it is unclear if the term “then” is meant to limit the method such that step b) occurs immediately after step a) and that therefore no intervening steps can occur. If this is the case it is unclear how one can contact only the thermostable polymerase, alone, with the sample nucleic acid, but not the dNTP or the buffer. Without an intervening extraction step, it is unclear how one would be capable of contacting only the polymerase with the sample nucleic acid without also contacting the dNTP and the buffer with the nucleic acid as well. The specification does not provide any guidance regarding such, nor does the specification provide any description of only contacting “said thermostable polymerase” with the sample nucleic acid. Accordingly, the recitation appears to introduce new matter into the claimed invention.

Claim Rejections - 35 USC § 102

7. Claims 60 and 61 are rejected under 35 USC 102(e) as being anticipated by Hoeltke (Hoeltke et al; US Patent 5,814,502).

Hoeltke teaches stabilized compositions already mixed for labeling nucleic acids comprising an enzyme such as Taq DNA polymerase (col. 2, line 40), one or more dNTPs and a buffer (col. 2, lines 33-34) and are stable on storage (col. 2, lines 29-31). Hoeltke teaches that 4 to 20 ul of the reaction solution are usually pipetted to the corresponding DNA samples (col. 4, lines 4-5).

8. Claims 60 and 61 are rejected under 35 USC 102(e) as being anticipated by Gelfand (Gelfand et al; US Patent 5,618,703) as evidenced by Chang (Chang et al; Clinica Chimica Acta, vol. 373, 158-163, 2006).

Gelfand teaches methods of performing multiple reverse transcription reactions wherein reagents are added in a mix comprising a thermostable polymerase, such as Tth or Taq, dNTPs, and a buffer salt. (see cols 27, 28, 30 and 31). Gelfand teaches the mixes are prepared and that aliquots are taken and contacted with sample nucleic acids or that sample nucleic acids are added to the mixes.

The recitation of “taking from storage” is not defined by the specification. The specification provides different examples of storage, which include storage for 4 weeks and up to 2 years, as well as storage conditions ranging from room temperature to –20 °C. The term “storage” as used by the art, is not limited to any particular length of time. For example, Chang teaches storage of blood and use “within 4 h” (page 159, col. 2, section 2.2). Further, as taught

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by the instant specification, the term is not limited to any particular storage temperature, but can include a wide range of temperatures. Accordingly, the term has been given it's broadest reasonable interpretation to include storage for any length of time, from a few seconds, to hours, days, or years, as evidenced by Chang which teaches storage when stored components are used "within 4 hours". Should the components have been used from storage within a few seconds, or minutes, this would not change the fact that they had been "stored".

Conclusion

9. No claims are allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jehanne Sitton whose telephone number is (571) 272-0752. The examiner can normally be reached Monday-Thursday from 8:00 AM to 5:00 PM and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571) 272-0735. The fax phone number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and

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history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Jehanne Sitton
Primary Examiner
Art Unit 1634

Jehanne Sitton
9/18/06